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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
097646,924	09/25/00	RASPE	E MERCK 2157

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EXAMINER
CHUNDURU, S

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 03/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/646,924

Applicant(s)

RASPE ET AL.

Examiner

Suryaprabha Chunduru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

DETAILED ACTION

1. The Preliminary Amendment (Paper No. 3) and the Information Disclosure Statement (Paper No. 4) filed on September 25, 2000 and February 12, 2001 respectively, have been entered and considered.

2. The Disclosure is objected because of the following informalities:

Oath/Declaration

(i) The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because page No.4 of the Oath/Declaration is Missing.

Drawings

(ii) The drawings are objected to because:

(a) no label for x-axis in Fig. 1 and 14;

(b) no label for the '←' in Fig. 7, 8, 9 and 10.

Correction is required.

Claim Rejections - 35 USC § 101

3. Claims 1 and 2 provide for the use of ROR receptors, Claims 14-17 provide for the use of a substance for the preparation of a pharmaceutical composition, capable of modulating, capable binding and a method of screening, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A

claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1, 2 and 14-17 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(a) Claims 1, 3, 8 and 14-17 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 3, 8 and 14-17 are confusing for referring to the subject matter in the term "and/or". Thus it is unclear how the claims can simultaneously encompass all of these limitations. The claims should refer to the subject matter in the alternative only, the replacement of the term "and/or" with "or" or the addition of dependent claims are suggested.

(b) Claims 1, 2 and 14-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite and vague because the claims recite a use without delimiting how this use is actually practiced and claims are written in the passive tense. Method claims should recite positive, active

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process steps, see Ex parte Erlich 3 USPQ 2d 1011. This rejection may be overcome by amending the claims to recite the active tense.

(c) Claims 3-7, 8 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite and vague because the claims 3-7 and 12 recite 'measured by any appropriate means' and claim 8 recites "binding" tests without delimiting to what method steps are actually practiced. Method claims should recite positive, active process steps, see Ex parte Erlich 3 USPQ 2d 1011. This rejection may be overcome by amending the claims to recite the active tense.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mak et al. (USPN. 5,700,682) and in view of Vu-Dac et al. (J.biol.chem., 272(36):22401-22404,1997).

Mak et al. teach a method for retinoid X receptor agonists and antagonists wherein they disclose screening is accomplished by retinoid X receptor (RXR) expression utilizing yeast-based expression system (see column 4, lines 16-18). They also disclose (i) construction of yeast expression vector for retinoid X receptor α (RXR α) (see column 8, lines 63-67 and column 9, lines 1-29); construction of reporter plasmid with two copies of apolipoprotein AI gene site A which has been shown to function as retinoic acid response element in mammalian cells (see column 9, lines 31-45); transcription assay in yeast strains containing RXR α receptor expression construction and the reporter plasmid (see column 10, lines 40-46); screening for antagonists or agonists of RXR α receptor (see column 14, lines 31-48); transfection with expression vectors (see column 15, lines 63-67 and column 16, lines 1-10). They further disclose the response of apo AI site A on the orphan receptor HNF4, a transcription factor and a member of the steroid-thyroid hormone receptor superfamily (see column 7, lines 25-34) and indicated RXR α agents may be useful for the prevention or regression of atherosclerosis (see column 6, lines 58-67). However, they did not disclose ROR receptors and binding domains.

Vu-Dac et al. teach transcriptional regulation of apolipoprotein A-I gene expression by RoR α receptor wherein they disclose ROR receptor isoforms and their binding to response elements consisting of a 6bp AT-rich sequence in their N-terminal domain transactivation properties (see page 22401, paragraph 3). Further they disclose that ROR α target gene is involved in lipid and lipoprotein metabolism (see page 22404, paragraph 2).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to modify a method of screening retinoic X receptor agonists and antagonists with ROR receptors to achieve expected advantage of rapid screening of

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substances that modulate the ROR receptor expression. The motivation for this would have been an approach to detect ROR receptor modulators.

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 703-308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Suryaprabha Chunduru
March 12, 2001



**EGGERTON A. CAMPBELL
PRIMARY EXAMINER**